Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

COVID-19 vaccine trials in Africa

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For more on the **AAS consultation** see https://www.aasciences.africa/sites/default/files/2020-04/Research%20and%20Development%20Goals%20for%20COVID-19%20in%20Africa.pdf

For the **study of stakeholder engagement** see https://onlinelibrary.wiley.com/doi/full/10.1111/dewb.12283

On Aug 17, 2020, screening began for participants to enrol in the mid-stage study of an experimental COVID-19 vaccine by Novavax, a US drug developer of next-generation vaccines for serious infectious diseases, at Witwatersrand University (Wits) in Johannesburg, South Africa. A US$15 million grant towards the trial was awarded to Novavax by the Bill & Melinda Gates Foundation. 2665 healthy adults and nearly 240 medically stable, HIV-positive adults will be enrolled.

"The major motivation for COVID-19 vaccines being evaluated at an early stage in South Africa is to generate evidence in the African context on how well these vaccines work in settings such as our own", says principle investigator of the Novavax clinical trial Shabir Madhi, Wits Professor of Vaccinology.

"The clinical trial will enable informed decision making when advocating for the adoption of this NVX-CoV2373 vaccine candidate or other COVID-19 vaccines in African countries, once they are shown to be safe and effective", says Madhi, also executive director of the South African Medical Research Council Vaccines and Infectious Diseases Analytics (VIDA) research unit at Wits.

The trial is the second one in South Africa, with a third trial for Ad26.COV2-S, a Johnson & Johnson product, set for September, 2020. The first trial, also led by Madhi, of a COVID-19 vaccine in South Africa commenced on June 23, which was the first vaccine candidate to be tested in Africa. This trial (Ox1Cov-19 Vaccine VIDA trial) is in collaboration with Oxford University and the Jenner Institute.

Additional vaccine research in Africa is already in the pipeline. Oxford University is awaiting final clearance to conduct clinical trials in Kenya. Uganda's Vaccine Research Institute, led by Professor Pontiano Kaleebu, is aiming to start a vaccine clinical trial in December, 2020, in collaboration with the Imperial College London.

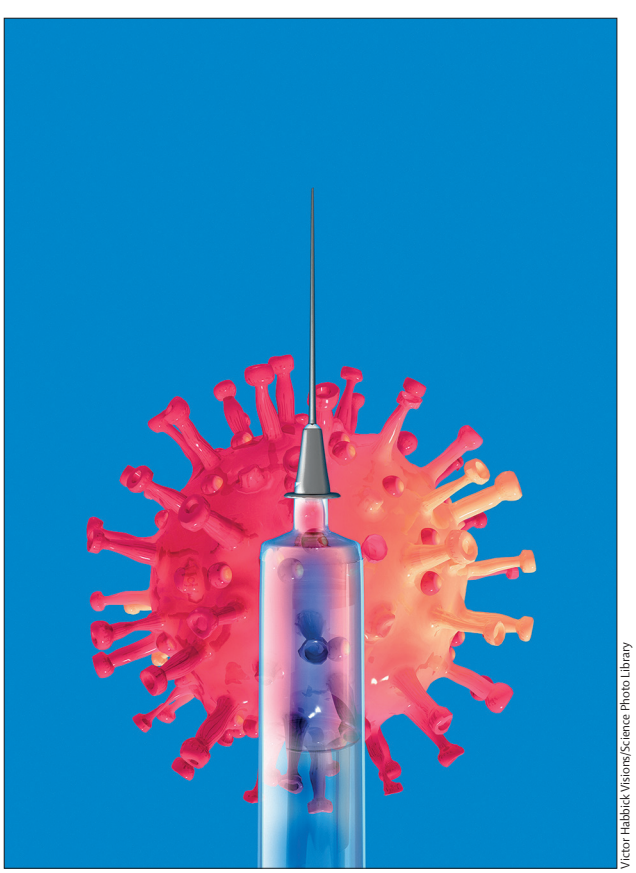
Vaccine development and trials emerged as a key research priority for COVID-19 in Africa, after a consultation was released in April, led by the African Academy of Sciences (AAS) based in South Africa and the African Union Development Agency (formerly known as NEPAD), involving more than 600 researchers and policy makers.

Africa, similar to all other parts of the world, faces a pandemic of uncertain duration. Health systems in Africa are particularly overstretched and the social measures to limit transmission are placing a heavy socioeconomic burden on vulnerable populations, says Kevin Marsh, AAS senior advisor. "Vaccines offer a way of potentially bringing this situation to an end", says Marsh. "Historically Africa has too often been a passive recipient of vaccines developed and tested elsewhere. African researchers and policy makers want to play a leading role in the international effort to develop vaccines, and it is essential that potential vaccines be trialled in the populations in which they are intended to be used", he told the *Lancet Respiratory Medicine*.

"Testing vaccines on the continent ensures that sufficient data are generated on the safety and efficacy of the most promising vaccine candidates for the African population so they can be confidently rolled out in Africa once approved", says Dr Richard Mihigo, coordinator for Immunization and Vaccine Development at the WHO Africa Regional Office. "This is by no means the first vaccine to be developed or tested in Africa", he says, noting the conjugate meningitis A vaccine, launched in 2010, that underwent clinical trials in several African countries and has since been used to immunise more than 300 million people. "The Ebola vaccine, which was also tested in Africa, has helped to end the Democratic Republic of the Congo's largest Ebola outbreak", adds Mihigo.

One study observed a "critical need for competency to conduct clinical trials in sub-Saharan Africa because the biological, economic, and sociopolitical factors associated with the emergence of diseases, epidemics, and pandemics are over-represented in many countries of the region".

Mihigo says, "the competency is there as clinical trials in Africa are being performed according to international standards, following strict WHO guidelines, which include ethical guidelines requiring informed consent for anyone participating in the trials. As a continent, we've come a long way in building an infrastructure for monitoring vaccine trials. Still, there are never any guarantees... there is a possibility for some flaws



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For more on the **consortium** see https://africacdc.org/news-item/african-union-commission-launches-consortium-for-covid-19-vaccine-clinical-trial/

in implementation. But, there is no reason to expect that trials taking place anywhere in Africa would be less ethical or less effective than in any other part of the world", Mihigo added.

"There is no difference in the rigour accounting for ethical issues in vaccine trials in Africa compared with other continents", Marsh agrees. Over the last 20 years, African researchers have conducted many vaccine trials to international standards and have taken into account complex contextual issues.

In the quest to provide appropriate vaccines to its people, in July the African Union (AU) launched a new consortium to bring together global vaccine developers, funders, and African organisations that conduct clinical trials. The Africa Centres for Disease Control and Prevention (CDC) Consortium for COVID-19 Vaccine Clinical Trial (CONCVACT) aims to ensure that more than 10 late-stage COVID-19 vaccine trials are conducted in Africa to gather enough data on the safety and efficacy of vaccine candidates among African populations.

"It is critically important for academics, researchers, and the private sector to work together and use all available platforms for the development of a COVID-19 vaccine, which will enable Africa to regain momentum for achieving the goals of the continental integration agenda", said Moussa Faki Mahamat, AU chairperson.

The AAS Clinical Trials Community states that only 2% of clinical trials globally, for all types of vaccines, take place in African nations and the WHO Africa Region. At the end of August, Africa had surpassed 1 million cases of COVID-19—an indication of the need to have vaccines tested on relevant populations. According to WHO, as of Aug 28, 2020, there are 33 COVID-19 vaccine candidates under clinical evaluation, of which two are in Africa.

"The sponsors of these vaccine trials will need to readily find trial sites that have the capacity, capability, and experience to generate high quality data that could be included in regulatory dossiers that will be assessed by the international scientific and regulatory community", says Colin Pillai, programme consultant for the AAS Clinical Trials Community. "These trials need to be conducted in geographical areas with laboratory confirmed cases of COVID-19", Pillai explains, adding that the AAS is actively collaborating with the Africa CDC to help with this process via its clinical trials community platform. "This is an online resource that is a one-stop source of an online, comprehensive, transparent, and accessible database that promises to be a single source of information on African clinical trial sites and their capabilities, as well as the regulatory and ethical landscape to guide decision making by stakeholders", he says.

"The good news is that so-called ready-now trial sites already exist in multiple countries across the continent. There is also an expectation that sponsors will help build capacity at the sites that do not currently have the expertise or the infrastructure to conduct these types of trials", says Pillai.

On the implications of the two trials currently underway in Africa, Marsh says they will provide key data on how the vaccine performs in populations that have the most need of protection from COVID-19. However, given the urgency of the situation, with a large number of potential approaches and a lack of clarity on which vaccine will be best suited, it is important that larger trials are conducted in diverse populations across the continent. "The more trials we conduct, the more chances we have of finding an effective vaccine", says Mihigo. He adds that it is important to evaluate as many vaccines as possible, because researchers cannot predict how many will turn out to be viable.

African scientists are playing a critical role in the design and implementation of these vaccines trials and this will definitely increase the capacity of the region to contribute to the global search for vaccines in the response against the COVID-19 pandemic.

"Other research for COVID-19 treatment is ongoing in Africa", says Mihigo. For example, a trial is underway in South Africa to investigate the effectiveness and safety of using plasma from people who have recovered from COVID-19 as a treatment for patients with moderate to severe COVID-19 pneumonia. Researchers from the University of Cape Town are working with the South African National Blood Service and the Western Cape Blood Service on this effort.

The Africa CDC Consortium proposes the dismantling of crucial barriers to clinical trials through establishing partnerships with leading vaccine developers to host selected late-stage trial sites in Africa, identifying countries where opportunities for trials are most promising, and setting up an independent review board for guidance. But, as Amira Elfadil Mohammed, Commissioner for Social Affairs at AU says, "getting a vaccine is not an end in itself. There is [an] urgent need for global solidarity, cooperation, and appropriate regulation to ensure equitable access to a potential COVID-19 vaccine".

Munyaradzi Makoni